REMARKS

After entry of this amendment, new claims 12-30 are pending. Claims 1-11 are cancelled without prejudice or disclaimer.

Support for the added claims is found as follows:

Added Claims	Support in the Specification
Claim 12	Page 11, lines 37-40; page 12, line 36-46; page 13, lines 1-15; former claims 1-2
Claim 13	Former claim 2
Claim 14	Former claim 3
Claim 15	Former claim 4
Claim 16	Page 12, lines 29-39; page 13, lines 11-32; page 14, lines 24-33; page 15, lines28-32; former claims 5-6
Claims 17-18	Former claims 5-6 and page 4, lines 26-27
Claim 19	Former claim 7
Claim 20	Former claim 8
Claim 21	Former claim 9
Claim 22	Former claim 10
Claim 23	Page 1, lines 30-35; page 26, lines 15-22; former claims 1, 5-6, and 11
Claims 24-25	Page 4, lines 26-27
Claims 26-27	Page 1, lines 30-35; page 26, lines 15-22; page 2, lines 5-12; page 4, lines 22-24; page 5, lines 13-20; page 12, lines 29-39; former claim 9
Claims 28-30	Page 6, lines 45-47; page 7, lines 1-27; page 12, lines 29-39; page 13, lines 11-32; page 22, lines 4-44; page 24, lines 9-12 and 40-41; page 25, lines 1-2; former claims 1-2, 4, 5-6, and 9.

No new matter has been added.

As requested by the Examiner, the specification has been amended to include the priority applications.

Claim Objections

The Examiner objected to former claims 8-11 as being improperly dependent. In light of the new claims this objection is believed to rendered moot.

Rejections under 35 U.S.C. § 112, first paragraph

Former claims 2-4 and 6-7 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement and for lack of an enabling disclosure. Applicants respectfully traverse the rejections. The new claims are believed to avoid both rejections.

Written Description

The Examiner argues that because of the recitation in the former claims of variants to SEQ ID NO: 1 or 2 with 60% identity that Applicants are not in possession of the claimed invention. In order to expedite prosecution, Applicants have amended the claims without prejudice or disclaimer. The new claims do not recite 60% identity. In light of these amendments, these rejections are believed to be rendered moot. Reconsideration is respectfully requested.

The Examiner further argues that the specification fails to describe a representative number of species. The applicable test for written description is stated in the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, Written Description Requirements" 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001) as cited by the Examiner. As there indicated, the written description requirement for a claimed genus can be satisfied in a number of alternative ways, such as through sufficient description of a representative number of species by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics.

The new claims are directed to a method of increasing total oil content in plants by transgenic expression of a polypeptide from yeast or a nucleic acid encoding the polypeptide which expression increases total oil content in a plant or part thereof as compared to a wild type plant and to transgenic expression cassettes comprising the nucleic acid. The specification describes that using the nucleic acid sequence of SEQ ID NO: 1 encoding the polypeptide of SEQ ID NO: 2 enhances the production of triacylglycerol (TAG), by genetic transformation of

an oil-producing organism with said sequence in order to be expressed in this organism, resulting in an active protein that increases the oil content of the organism. See specification at page 4, lines 26-31. Furthermore, the specification discloses that the gene product, referred to as a TAG synthesis enhancing protein (TEP), is most likely not itself catalyzing the synthesis of TAG, but its presence elevates the amount of TAG synthesized by other enzymes. See specification at page 4, lines 38-41. The specification additionally describes and exemplifies that the expression of the polypeptide as set forth in SEQ ID NO: 2 increases total oil content in two organisms. The specification additionally exemplifies that when gene expression was disrupted in a mutant yeast the triacylglycerol content was reduced. Thus, the specification provides a correlation between structure (the gene itself as set forth in SEQ ID NO: 1, which encodes SEQ ID NO: 2) and the function of the gene, *i.e.* modifying oil content.

The Examiner also bases the written description rejection on the invention allegedly being described solely in terms of a method of its making coupled with function citing MPEP § 2163, or in terms of the invention not being reduced to practice until defined by "its physical or chemical properties" (*e.g.* a DNA sequence) citing *Amgen v. Chugai*, 18 U.S.P.Q.2d 1601 (Fed. Cir. 1991). In *Amgen*, the Federal Circuit held that it is not sufficient to define a gene solely by its biological property, and that conception of a generalized approach for screening a DNA library for a particular gene is not conception of a purified and isolated DNA sequence. In the present application, the specification discloses a purified and isolated DNA sequence (SEQ ID NO: 1) and the polypeptide encoded by this gene (SEQ ID NO: 2), thereby providing a description of the DNA itself and the polypeptide. Furthermore, in the present application, the nucleic acid sequence is not solely defined by function or by a general method for identifying or obtaining a gene. Rather, the actual sequence is disclosed in the specification and as explained above has been correlated to function. Therefore, *Amgen* is inapposite to the present application.

For these reasons, it is submitted that the claims as amended are in compliance with the written description requirement. Reconsideration and withdrawal of this rejection is respectfully requested.

Enablement Rejection

The Examiner argues that because of the recitation in the former claims of variants to SEQ ID NO: 1 or 2 with 60% identity that the specification does not provide enablement for the claimed invention. In order to expedite prosecution, Applicants have amended the claims without prejudice or disclaimer. The new claims do not recite 60% identity. In light of these amendments, these rejections are believed to be rendered moot. Reconsideration is respectfully requested.

The Examiner broadly characterizes the invention as relating to methods and compositions relating to transgenic plants. The Examiner alleges that the former claims include sequences from any species with any sequence having any function including sequences encoding proteins with no total oil increasing activity. Applicants respectfully submit that this is no longer applicable since the present claims are drawn to methods and expression cassettes where a polypeptide from yeast or a nucleic acid encoding the polypeptide when expressed transgenically results in increased oil content in plants.

The Examiner further argues that the quantity of experimentation would be very large to identify homologs, clone the homologs, do enzyme assays to confirm enzyme activity, select the homologs with high activity, transform plants, and screen for transformants with high activity. The Examiner again points to the 60 % identity recited in the former claims. Applicants submit that in light of the present claims this is no longer applicable.

Furthermore, the specification provides guidance on identifying, isolating, and analyzing functional equivalents or homologs of the genes of the invention as seen on page 12 line 22 through page 14 line 7. Additionally, one skilled in the art would recognize that screening and testing for enzyme activity in microorganisms and plant species is routine and is not undue experimentation. For instance, Examples 1-3 provide assays for determining activity, describe transformation of yeast and plants and screening of the transformants for activity. Transformation and regeneration of plants is further described on page 22 line 13 through page 25 line 6, and is well known by one of ordinary skill in the art. The same applies to screening

and testing the activity of homologs or functional equivalents of the sequences as presently claimed. It is therefore submitted that such screening and testing is "routine" on this record absent evidence and reasoning to the contrary by the USPTO. Compare, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not "undue experimentation;" the involved experimentation can be considerable, so long as "routine"). The test for whether experimentation is "undue" is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982). In the present case, the specification provides detailed guidance and teaches in the Examples, as explained above, the types of routine assay which are employed to confirm enzyme activity and additionally working examples showing activity. The detailed guidance provided in the present specification and the routine nature of the screening for activity overcome the unpredictability alleged by the Examiner.

The Examiner alleges that the data provided are likely no more that a plan or invitation to experiment based on the alleged failure to teach the enzymatic activity of YJR098c and lack of data beyond a mere statement of altered oil levels citing to *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F. 3d 1362 (Fed. Cir. 1999); MPEP 2164.06(b). Applicants respectfully disagree. As explained in MPEP 2164.06(b), in *Enzo*, the patents dealt with antisense technology in regulating three genes in *E. coli* while the claims of the patents encompassed application of antisense methodology in a broad range of organisms containing genetic material which is capable of being expressed, and where the record included notable examples of the inventor's own failures to control the expression of other genes in *E. coli* and other types of cells. Antisense technology is totally different than the gene expression of the present invention. In the present application, Applicants have demonstrated in two different organisms that when the gene of the invention is expressed, total oil content is increased. Furthermore, Applicants have demonstrated that when the gene is disrupted the activity is also modified. Thus, Applicants have provided actual working examples and data demonstrating the method and use of the gene and expression

cassettes as presently claimed, not just a plan or invitation to experiment. Therefore, *Enzo* is inapposite to the present application.

In view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the present claims without undue experimentation. On these facts, an analysis under *In re Wands* supports enablement.

Rejections under 35 U.S.C. § 112, second paragraph

Former claims 1-7 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In light of the amendment, Applicants submit that the indefiniteness rejections have been addressed. The new claims are believed to avoid the rejections. Reconsideration is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. The Examiner is invited to telephone the attorney listed below if there are any further issues before allowance.

Accompanying this response is a petition for a three-month extension of time to and including June 1, 2007 to respond to the Office Action mailed December 1, 2006 with the required fee authorization. A fee sheet authorizing payment for the new claims is also enclosed.

No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00140-US from which the undersigned is authorized to draw.

Respectfully submitted,

By

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